TIME TO BOND 4D ULTRASOUND LIMITED

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Inspection report

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This report describes our judgement of the quality of care at this service. It is based on a combination of what we found when we inspected, information from our ongoing monitoring of data about services and information given to us from the provider, patients, the public and other organisations.

Ratings

Overall rating for this location	Good
Are services safe?	Good
Are services effective?	Good
Are services caring?	Outstanding
Are services responsive to people's needs?	Good
Are services well-led?	Good

Summary of findings

Overall summary

We have not previously inspected this service. We rated it as good because:

- The service had enough staff to care for women and keep them safe. Staff had training in key skills and managed safety well. The service controlled infection risk well. Staff assessed risks to women, acted on them, and kept good care records.
- Staff provided good care to women that was based on an ethos of continuous improvement. The registered manager monitored the effectiveness of the service and made sure they maintained competency in line with international standards. Staff worked well together for the benefit of women, supported them to make decisions about their care, and had access to good information. Key services were available flexibly.
- Women were respected and valued as individuals. Staff empowered them as partners in their care, practically and emotionally. All aspects of care were individualised, and staff were highly skilled in providing emotional support.
- The service planned care to meet the needs of people who used the service, took account of women's needs, and made it easy for people to give feedback. People could access the service flexibly.
- The service had an overarching vision that focused on the unique needs of each individual who used the service. Staff were clear about their roles and accountabilities. The service engaged well with women to plan and manage services and staff were committed to improving services continually.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic and screening services	Good 	We rated this service as good because it was safe, effective, caring, responsive and well led. Please see the main summary.

Summary of findings

Contents

Summary of this inspection

Background to TIME TO BOND 4D ULTRASOUND LIMITED

TIME TO BOND 4D ULTRASOUND LIMITED is the name of the service and the provider. The service opened in February 2022 and is a single speciality independent healthcare provider offering 2D, 3D and 4D baby scanning to self-funding women for non-diagnostic purposes. Scans include bonding, gender determination, foetal growth, or reassurance. Ultrasound services are provided for women aged at least 18 years and at a minimum of 6 weeks gestation.

The service provides access to a range of other services including non-invasive prenatal screening (NIPTS), stem cell blood sampling for disease prevention, and paternity testing.

The service is staffed by an ultrasound technician, who is the registered manager, and an office manager. It is registered to provide the following regulated activity:

- Diagnostic and screening procedures

Services are provided from a specially designed clinic that includes a spacious ultrasound suite with space for accompanying relatives, a comfortable waiting area with information on scanning options, and a private space to discuss care.

How we carried out this inspection

We carried out a comprehensive inspection of the service under our regulatory duties. The inspection team comprised of a CQC lead inspector, a specialist advisor and off-site support from an operations manager. We gave the service short notice of the inspection because we needed to be sure it would be in operation at the time we planned to visit.

You can find information about how we carry out our inspections on our website: https://www.cqc.org.uk/what-we-do/how-we-do-our-job/what-we-do-inspection.

Outstanding practice

We found the following outstanding practice:

- Staff were demonstrably passionate and empathetic and worked tirelessly to meet individual needs, including in complex circumstances. They recognised the impact anxiety and uncertainty had on mental health and worked with women to reduce this using innovative approaches that exceeded usual ultrasound scanning protocols and expectations.
- The service was demonstrably forward-thinking, and staff worked with national and international organisations to guide practice and underpin policies, which reflected the leading edge of the field.
- The provider recognised the importance of building effective, managed relationships with local NHS services, including early pregnancy units and maternity wards. They liaised directly with staff to ensure they understood the nature of this service and the provider's standards. This helped to address misconceptions of the independent healthcare sector and meant women experienced more streamlined referrals between this service and secondary care.

Our findings

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Diagnostic and screening services	Good	Good	☆ Outstanding	Good	Good	Good
Overall	Good	Good	☆ Outstanding	Good	Good	Good

Good

Diagnostic and screening services

Safe	Good
Effective	Good
Caring	Outstanding
Responsive	Good
Well-led	Good

Is the service safe?

Good

We have not previously inspected the service. We rated safe as good.

Mandatory training

The service provided mandatory training in key skills to all staff and made sure everyone completed it.

Staff received and kept up to date with their mandatory training. Mandatory training was comprehensive and met the needs of women and staff. The training programme had 12 modules and included infection prevention and control (IPC), health and safety, and moving and handling in addition to specialist clinical training.

Staff worked together to ensure their training was up to date and identified opportunities for further development. They completed training updates when processes changed, such as with the introduction of new equipment or IT systems.

Safeguarding

Staff understood how to protect women from abuse and the service worked well with other agencies to do so. Staff had training on how to recognise and report abuse and they knew how to apply it.

Staff undertook training on how to recognise and report abuse and could give examples of how to protect women from harassment and discrimination. Both members of staff maintained level three adult and child safeguarding training.

Staff provided examples of when they had acted on safeguarding concerns. Their actions had protected women from potential harm, including instances where they suspected coercion or control. For example, staff had made an urgent safeguarding referral when they found a woman had falsified their age and would not consent to a scan without the presence of 2 men. They maintained contact with the local authority safeguarding team whilst they investigated.

Staff knew how to identify adults and children at risk of, or suffering, significant harm. They adhered to a safeguarding policy that required online bookings to be made at least 24 hours in advance. If someone tried to make a booking with less notice, the service required a telephone conversation with the individual to ensure they met safe scanning criteria and were not under coercion or duress.

Staff knew how to make a safeguarding referral and who to inform if they had concerns. The registered manager maintained up to date contact details for the local safeguarding team and had established links with safeguarding leads at local NHS trusts in the event of an urgent referral.

Discreet signage in the clinic let women know they could ask for private space to talk with staff. The service displayed contact details of non-profit specialist organisations including for assistance with issues such as domestic violence, trafficking, and female genital mutilation (FGM). Staff kept up to date details for NHS services that provided urgent support for women at risk of, or who had experienced, FGM. They followed the latest guidance from the National FGM Centre in partnership with the Local Government Association to make sure policies reflected best practice.

The service had an up-to-date chaperone policy that reflected the diverse needs of women. The office manager was trained to chaperone, and women could arrange a healthcare professional to chaperone them with prior discussion.

Cleanliness, infection control and hygiene

The service controlled infection risk well. Staff used equipment and control measures to protect women, themselves, and others from infection. They kept equipment and the premises visibly clean.

Clinical areas were clean and had suitable furnishings which were clean and well-maintained. Staff used a daily IPC checklist to ensure all areas were cleaned and sanitised on days the clinic was open. They used a weekly process for deep cleans of clinical areas.

Cleaning records were up to date, and a rolling programme of audits demonstrated that all areas were cleaned regularly and effectively.

Staff carried out a monthly hand hygiene peer audit on each other as a quality tool to monitor adherence to national 'key moments' best practice. Audit results demonstrated consistently good standards. The service displayed hand washing guidance in line with World Health Organisation standards at each sink.

Staff followed good infection control principles including the use of personal protective equipment (PPE). For example, the sonographer wore gloves during scanning and antibacterial gel on their hands between scans.

The service was compliant with the Control of Substances Hazardous to Health 2002 Regulations. For example, staff used a colour coding system for mops and cleaning equipment. The service had an appropriate locked area to store cleaning chemicals.

The sonographer used a nationally accredited antibacterial system to sanitise ultrasound probes and the scanning couch between scans. They carried out a full clean of the clinical space at the end of each list.

Environment and equipment

The design, maintenance and use of facilities, premises and equipment kept people safe. Staff were trained to use them. Staff managed clinical waste well.

The design of the environment followed national guidance. Scanning and blood tests took place in a clinical room that met Department of Health and Social Care (DHSC) standards on the clinical environment.

Staff carried out daily safety checks of specialist equipment. Service agreements were in place for planned servicing and a call-out plan was in place in the event of equipment failure.

The manager stored phlebotomy equipment in a locked unit with restricted access. The organisation that operated a laboratory for non-invasive prenatal screening (NIPTS) supplied the equipment and disposed of expired items on demand.

The service had suitable facilities to meet the needs of women and those accompanying them and to provide safe care.

Staff disposed of clinical waste safely. The service had a contract with a third-party organisation to collect and dispose of hazardous waste. The service was fully compliant with the DHSC health technical memorandum and the Health and Safety Executive Health and Safety (Sharps Instruments in Healthcare) Regulations 2013 in relation to sharps waste. The clinical waste disposal contract included the disposal of sharps waste.

The team maintained a comprehensive environment and premises risk assessment that included fire safety. The service underwent a fire risk assessment within the previous 12 months and staff regularly tested the fire alarm, emergency lighting, and checks of escape routes.

Staff had a system for stock control and rotation for consumable items. This meant the service could always meet demand.

Staff followed safe procedures for children visiting the service and all areas were modified for child safety.

Assessing and responding to patient risk

Staff completed and updated risk assessments for each woman and removed or minimised risks. Staff knew what to do and acted quickly when there was an emergency.

Staff provided care using up to date risk assessments appropriate to the service. Specific risk assessments were in place for blood-drawing procedures for NIPTS and for ultrasound services. These followed national guidance and considered remote but not impossible risks for each procedure. Staff asked about allergies to latex and used non-latex probe covers if the woman being scanned had sensitivities.

Staff responded promptly to any deterioration in a patient's health. The service offered reassurance and bonding scans without a diagnostic element and so acute illness was unlikely. However, both members of staff were trained in first aid and the clinic had a first aid kit and biological spill kit.

The sonographer had clinical emergency training. This included level three paediatric first aid training, gynaecology ultrasound emergency training and early pregnancy emergencies. Both members of staff had completed basic life support training.

The local area had automatic external defibrillators (AEDs) in public spaces that could be accessed with codes provided in an emergency by 999. The service maintained an up-to-date list and map of each AED site in the reception area, all of which could be reached quickly on foot in the event of an emergency.

Staff completed risk assessments for each woman at the point of booking. This included a check of relevant medical history and information such as use of cigarettes, alcohol, and recreational drugs. Staff also asked about allergies, history of fainting and for confirmation of registration on an NHS maternity pathway. The service required a pregnancy to be at a minimum of 6 weeks for an early reassurance scan and 14 weeks for a gender scan.

Good

Diagnostic and screening services

Staff checked the identity of each woman using British Medical Ultrasound Society (BMUS) national guidance. This included a cross-reference of the procedure booked with what the individual requested on the day and a check of their date of birth and address. Where staff suspected a woman was under the minimum age of the clinic, they checked photographic ID.

NIPTS was used as a preventative measure to help identify early pregnancy risks. The service carried out blood tests for the screening and arranged for a courier to transport the sample to a laboratory for testing. Staff carried out a risk assessment and consent process for women who requested this service to ensure they understood that results and onward care were provided by a third-party organisation. This ensured there was clear separation of each responsibility for the providers involved.

The sonographer maintained records of referrals to NHS gynaecology services and followed up with women to make sure they received prompt care. In the previous 12 months they made 18 referrals, most often because there was no foetal heartbeat or no growth.

The service was not registered to provide scans to women under the age of 18. Where staff received queries or attempted bookings, they referred people to another service that was equipped to provide care for this age group.

The sonographer managed risks associated with the higher power levels used by ultrasound equipment during doppler scans. The heat generated by such scans presented a risk to foetal health and the sonographer limited scanning time accordingly, including a policy not to listen to a foetal heart before 14 weeks gestation.

Staffing

The service had enough staff with the right qualifications, skills, training, and experience to keep women safe from avoidable harm and to provide the right care.

The registered manager was the sonographer and owner of the business. An office manager led reception, booking, and other administrative and operational duties. Both members of staff were trained appropriately for the care provided and worked together to meet demand.

Both members of staff had up to date Disclosure Barring Service (DBS) checks and the registered manager updated these every three years.

At the time of our inspection there were no bank, agency, or locum staff in post.

Records

Staff kept detailed records of women's care. Records were clear, up to date, stored securely and easily available to all staff providing care.

Ultrasound notes were comprehensive, and staff could access them easily. The service provided simple gender scans only and did not offer a diagnostics service. Scan reports reflected this.

In the event the sonographer found sinister pathology or evidence of a miscarriage, they provided a detailed report to the nearest early pregnancy assessment unit (EPAU), or to the nearest emergency department. Women consented to this in advance of a scan.

Good

Diagnostic and screening services

Records were stored securely. The service operated a paperless model and all scan imagery and data were stored in a secure digitally encrypted system. The platform had back-up protocols for systems failures and archived scans for 12 months in line with the provider's data management policy.

Medicines

The service did not store, manage, prescribe, or dispense medicines.

Incidents

The service had systems in place to manage safety incidents. Staff recognised and knew how to report incidents and near misses.

Staff knew what incidents to report and how to report them. The registered manager maintained an up-to-date incident management policy and a record system for incidents. Staff understood this system and the importance of the incident reporting process.

There had been 3 incidents in the previous 12 months, none of which resulted in patient harm. In each case the team reviewed the cause of the incident and identified learning for future prevention.

Staff understood the duty of candour. The service's incident management policy included the duty of candour and the registered manager said they would be responsible for implementing it.

Is the service effective?

Good

We have not previously inspected the service. We rated effective as good.

Evidence-based care and treatment

The service provided care and procedures based on national and international guidance and evidence-based practice.

Staff followed up-to-date policies to plan and deliver high quality care according to best practice and national guidance. The registered manager maintained policies and standard operating procedures and reviewed these regularly. They documented review dates, highlighted key changes, and shared updates with the office manager.

The sonographer was a member of the Institute of Sonography and Gynaecology (ISG), the International Society of Ultrasound in Obstetrics and Gynaecology (ISUOG), and the British Medical Ultrasound Society (BMUS). This ensured they had access to updates to best practice and national guidance. They benchmarked policies and procedures using ISG standards and monitored the National Institute for Health and Care Excellence (NICE) for updates and learning.

The service subscribed to the BMUS 'as low as reasonably achievable' (ALARA) principle. This meant the sonographer used the lowest possible output power and shortest scan times possible to achieve the required results.

The sonographer used up to date scanning protocols and reviewed these annually, or more often following an update to guidance or an incident. They followed BMUS best practice in the use of ultrasound equipment, including those that used doppler.

Good

Diagnostic and screening services

The service used quality assurance processes to ensure scanning equipment was in optimal condition. The sonographer listened to probes daily to ensure they provided the best heartbeat recordings possible.

Patient outcomes

Staff monitored the effectiveness of care. They used the findings to make improvements and achieved good outcomes for women.

Outcomes for women were positive, consistent, and met their expectations. The sonographer used national guidance to deliver scans and measured outcomes against women's expectations. Where clear scan images could not be achieved, the sonographer gave women time for a break to help the movement of baby. If this did not improve the scan, the service rebooked for a later date.

Staff used scan results to improve women's outcomes. The registered manager actively sought feedback from the local NHS trust following referrals to the early pregnancy assessment unit (EPAU) or the emergency department. This occurred in cases where they found or suspected a miscarriage or other urgent finding and helped ensure their practice supported timely care to address urgent need.

In the previous 12 months the sonographer reported a rescan rate of 7%. There were no national benchmarks for rescans in this type of service and instead the sonographer used feedback from women as a key outcome measure.

Staff worked openly and honestly with women to make sure they were aware of potential inaccuracies in results and to manage their expectations. For example, while gender reveal scans were usually reliable, there was a risk of incorrect results caused by certain conditions. Staff ensured women were aware of this before scans.

Competent staff

The service made sure staff were competent for their roles.

Staff were experienced, qualified, and had the right skills and knowledge to meet the needs of women. Both individuals had lengthy careers in healthcare and demonstrably used their knowledge of patient needs to provide highly individualised care.

There were no nationally accredited professional registration requirements for sonographers in baby scan services and instead the sonographer maintained a range of voluntary memberships.

Staff monitored updates from the Royal College of Obstetrics and Gynaecology as good practice to maintain an understanding of the wider sector. They accessed the latest training and scanning updates through memberships, which meant care was delivered at the leading edge of the sector.

The sonographer participated in the BMUS mentor programme. This was a reciprocal agreement with another BMUS-registered sonographer who peer reviewed scans, policies, and practices and shared learning from their own clinic. This was good practice and acted as a check and balance system appropriate for a service of this size.

Two members of staff operated the business and delivered the service. They maintained clear definitions of roles and responsibilities and worked together daily. This meant formal supervisions were rarely needed and instead they proactively discussed issues affecting the service, training needs, and ideas for improvement. The team held formal meetings quarterly to review the service, held a biannual peer review session, and checked professional development needs annually.

Good

Diagnostic and screening services

The service had not recruited new staff for some time. However, they had an up-to-date induction policy in the event recruitment took place.

The registered manager maintained competencies commensurate with their role and the services offered, such as level three advanced phlebotomy and training in foetal alcohol syndrome and child sexual exploitation.

Multidisciplinary working

Staff worked together as a team to benefit women. They supported each other to provide good care.

Staff worked across health care disciplines and with other agencies when required to care for women. They provided referrals to the neonatal unit or EPAU at nearby NHS trusts when scans revealed unexpected findings. They contacted the EPAU whilst the individual was still in the scanning unit and provided them with the instructions provided by the trust before they attended.

If the sonographer was unable to obtain a clear scan image and was concerned about the reasons for this, they referred women to the EPAU. The sonographer provided a detailed report in advance.

The service was aware lengthy delays to see midwives in the region presented women with significant challenges. The sonographer had established good working relationships with specialist services that provided women with options to reduce waiting times when they could be seen by another appropriate professional, such as other staff in maternity services.

Seven-day services

Services were available to support timely patient care.

The service operated on a flexible appointment basis seven days per week, with evening appointments on request. The online booking system was available 24 hours, 7 days a week.

Health promotion

Staff gave women practical support and advice to lead healthier lives.

The sonographer provided advice to women on healthy pregnancy, such as how to achieve good standards of nutrition and exercise. Information from specialist organisations was available in the clinic to support women with needs such as smoking cessation and eliminating alcohol during pregnancy.

Staff gave up to date information on mental health support for women and families during pregnancy. This included contact details for crisis services. The service provided details of a national NHS study about suicide risk during pregnancy as part of a transparent approach to discussing mental health and reducing stigma.

The provider had an agreement with a company that provided new parent gift packs that included access to online app-based support for self-care, and wellbeing during pregnancy.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

Staff supported women to make informed decisions about their care. They followed national guidance to gain women's consent.

Good

Diagnostic and screening services

Staff gained consent from women for their care and treatment in line with legislation and best practice guidance issued by the Society of Radiographers. The booking form required women to give signed consent and staff reviewed this when they arrived in the clinic.

Each appointment slot included time for staff to review the booking and consent details with the patient before a scan. Staff applied this during our inspection and were demonstrably skilled in ensuring women understood the consent process. They used a language translation tool to support women who did not fully understand the consent statement and ensured it was the individual themselves who consented, without influence from anyone accompanying them.

Informed consent information included details of the potential risks and benefits of each type of scan and staff tailored processes to individual bookings.

The service required women to have had initial maternity reviews with an NHS trust and to be at least 6 weeks into a pregnancy before scanning. Women declared this during the booking process and staff then sought consent to notify the NHS service of scan results where sinister pathology or other concerns were found.

Staff said if a woman could not consent, or they were not assured a woman understood what they were providing consent for, they would not proceed with a scan.

Staff received and kept up to date with training in the Mental Capacity Act as part of safeguarding training. They understood the relevant consent and decision-making requirements of legislation and guidance, including the Mental Health Act.

Is the service caring?

Outstanding ☆

We have not previously inspected the service. We rated safe as outstanding.

Compassionate care

There was a strong, visible, person-centred culture. Staff were highly motivated and inspired to offer care that was kind and promoted people's dignity. Relationships between people who used the service, those close to them, and staff were strong, caring, respectful and supportive. These relationships were highly valued by staff.

Staff were discreet and responsive when caring for women. They took time to interact with women and those close to them in a respectful and considerate way, carefully building a rapport in the context of an environment that could cause worry and stress in addition to positive emotions.

Women said staff treated them well and with kindness. During our inspection we saw women were overwhelmingly happy and appreciative of the service. Staff facilitated the environment to promote a calm, welcoming atmosphere and followed good practice to keep care and communication confidential. A woman who recently visited the service noted, "We had the most magical time."

Good

Diagnostic and screening services

Staff understood and respected the personal, cultural, social, and religious needs of women and how they may relate to care needs. For example, they understood the issues women experienced where a pregnancy conflicted with religious or cultural doctrine and worked to provide support.

Staff had a demonstrable focus on privacy and dignity that was deeply embedded across all elements of the service. The office manager ensured conversations with patients were discreet and could not be overheard by others. Scanning monitors used by the sonographer were fitted with privacy screens, which ensured information could be seen only by the person in front of the screen. The sonographer used a movable privacy screen in the scanning room to provide privacy when women had brought family or friends to accompany them.

Staff demonstrated natural, empathetic care to women and those accompanying them. During our inspection 1 person arrived late for their appointment and in considerable distress that they had missed their slot. The office manager offered them a drink and sat with them to reassure them they would still be seen. Feedback from patients indicated this was typical of the consistently high standards of care provided. Recent feedback included, “Professional, compassionate. Not just a business, they really care.”

Throughout our inspection staff demonstrated an effortless ability to build a rapport with each woman and those accompanying them. They remembered past conversations, which delighted people, and matched their approach to each individual. For example, some women preferred a familiar, informal relationship and others preferred a more clinical approach. During our inspection 1 woman told us, “[Staff] make a concerted effort to make the experience very positive. I’m pleased with how much they involve my partner too.”

Staff asked each woman to provide feedback. This was consistently positive. Recent examples included, “Your kindness will never be forgotten,” “[A] calm and intimate experience,” and “[Family member] attended with me on my visit and [staff] treated her with such respect.”

Emotional support

Staff provided emotional support to women and those close to them to minimise their distress. They understood women's personal, cultural, and religious needs and provided thoughtful, intuitive care.

Staff gave women and those close to them help and emotional support when they needed it. They recognised the emotional impact of different types of scan, such as learning the gender of a baby, and provided women with a gift after each scan. This promoted a positive approach to the scan and was presented in a ‘congratulations’ box. Staff marked the box with gender-neutral labelling where the individual did not yet want to know the gender.

Staff supported women who became distressed and helped them maintain their privacy and dignity. They always left a gap between bookings to provide time and space for women who needed support, such as for anxiety or if the scan identified a problem that needed specialist follow-up. This ensured women were not rushed and received care in an environment focused on their needs.

Staff maintained a private room for difficult discussions, such as in cases where they found no foetal heartbeat. They ensured women had all the information about ongoing support they needed before leaving the service. Feedback from women about this service was overwhelmingly positive. Recent feedback included, “[Staff provided] time and comfort during really difficult news,” and “Visit devastating but the care I received was brilliant.”

Good

Diagnostic and screening services

Staff understood the potential emotional and social impact that an uncertain pregnancy could have on women and those close to them. They offered genuine kindness and support to help reduce anxiety and worry. For example, they opened the clinic at short notice on a national holiday on request from an individual experiencing high levels of anxiety about their pregnancy. This meant the woman enjoyed a relaxed, anxiety-free holiday with their family.

Staff recognised the needs of women who were very anxious or experiencing distress during their pregnancy. For example, in cases where women requested multiple appointments that did not result in reassurance, the sonographer spent time with them to help alleviate their worry and identify a more appropriate plan for scanning. They helped women navigate NHS services that could provide clinical care to help meet their needs.

If the sonographer identified a miscarriage or foetal death, they did not release the scan images to the woman or their family and referred them either to an emergency department or their nearest NHS early pregnancy unit depending on the urgency of need. This ensured women received immediate emotional support.

The sonographer used links they had established with NHS maternity services to support women experiencing emotional distress. For example, when a woman presented with bleeding and was worried about a significant local waiting list, the service carried out an initial scan and then referred them urgently to a nearby NHS service. This reduced their wait by 5 days and meant the woman and their partner accessed the help they needed to reduce their worry.

During our inspection a woman had cancelled all plans for the rest of the day because they were nervous about scan results. Staff spent time with the individual, calmed their nerves, and helped to address their worries before they left.

The service had dozens of feedback messages from women who commented on the high standards of emotional support they had received. Recent comments included, “Thank you for reassuring me today after a scare at the hospital,” “Thank you for putting me at ease constantly,” and “I was welcomed with such warmth, they took the time to get to know me when I was an anxious mess.”

The sonographer worked closely with women to manage their emotional needs. For example, 1 individual asked for the live monitor facing the scanning couch to be switched off as they had high levels of anxiety about the results of the scan. The sonographer spent time talking to them to find out the cause of the anxiety and patiently addressed each of their worries.

Staff demonstrated thoughtful attention to detail when planning the service. For example, they took payment before the scan so as to avoid an uncomfortable discussion about this if the scan revealed bad news.

Understanding and involvement of women and those close to them

People who use services and those close to them are active partners in their care. Staff are fully committed to working in partnership with people and making this a reality for each person.

Staff made sure women and those close to them understood their care and procedures. They provided information in advance and just before a scan to make sure the procedure chosen was the best option for the individual. Staff made sure women understood the potential risks for each scan and supported them to make a choice with which they felt comfortable.

During our inspection staff worked well together to involve women and those with them in their care. For example, the office manager provided examples of the outputs from different types of scans, such as the images and sound

recordings available as well as aesthetic items. The sonographer explained what they were doing as they were doing it and encouraged women to tell them if they experienced discomfort. In such cases they paused the scan process and gave the woman time to get comfortable. Women reported positive experiences in the service. Recent feedback included, “It’s not like a conveyor belt. They give you time, space, and care.”

During our inspection staff recognised women who had been to the service previously and remembered their stage in the scanning process. This had a positive impact on women who told us they felt warmly welcomed and genuinely cared for.

The team tailored their welcome to each woman. For example, the office manager remembered a woman visiting for a late reassurance scan had been anxious at their last appointment. The individual appreciated the efforts of the team to make them as supported and comfortable as possible.

Staff went to great lengths to make sure women took the lead in the organisation and delivery of their care. For example, women often asked staff not to discuss certain aspects of their visit or scan with them when they had family present. Others wanted to make sure staff did not discuss the gender of the baby with them during the appointment. Staff worked to a high standard in this area and positive feedback reflected their efforts.

Staff were patient and informative when helping women and their partners decide on the best type of scan for their needs. For example, during our inspection staff worked with a couple to help them understand the differences between types of scan and what they would get out of each. Staff were skilful in providing patients with reassurance and enough information to help them make a decision without biasing the process.

Staff worked with women with specific needs or vulnerabilities to make sure they remained involved in decision-making. For example, women on holiday in the area from outside of the UK often approached the service to request scans. In such cases the team worked with them to ensure they could safely meet their needs. Staff had worked with women from a traveller community to help ensure they could provide scans when they did not have access to the internet. In such cases staff provided printed copies of consent and other required information and arranged alternative means of communication with women.

The sonographer used a life size baby doll to demonstrate to women how their baby was positioned within the uterus. Women often commented on the knowledge of the team. Recent feedback included, “Detailed from start to finish, [staff] have incredible knowledge.”

Is the service responsive?

Good

We have not previously inspected the service. We rated responsive as good.

Service delivery to meet the needs of people

The service planned and provided care in a way that met the needs of people and the communities served.

The service planned and organised services to meet the changing needs of the local population. The service provided transabdominal scans for women aged 18 years and above. Staff said they frequently received requests from younger women for scans and referred them to registered services equipped for younger people.

Good

Diagnostic and screening services

The service provided early gender DNA tests and non-invasive prenatal screening (NIPTS). This is a preventative test to identify early risks to pregnancy. The sonographer was a trained phlebotomist and took a blood sample in the clinic, which was then sent by courier to a laboratory. After this process, women dealt with the laboratory and any onward care was provided by the NHS or an independent hospital. The service ensured women understood this information in advance of carrying out the blood test. At the point of testing, the laboratory for NIPTS provided each woman with a named point of contact for the rest of the process.

The service minimised the number of times women needed to attend the clinic, by ensuring women had access to the required services on one occasion. For example, they offered NIPTS in the same appointment as the scan. If the sonographer could not get a clear scan because of the baby's position, they offered women time to walk around and try again.

Facilities and premises were appropriate for the services being delivered. The service was delivered in customised premises with a dedicated scanning room and comfortable waiting area for women and their loved ones. Children's toys were available for those accompanying women. All areas were accessible by those with mobility restrictions or who used a wheelchair.

The service had systems to help care for women in need of additional support or specialist intervention. Staff recognised the vulnerabilities of different individuals and communities and kept up to date with details for local specialist organisations. They provided onward referral or signposting and supported women to access help.

Staff monitored and took action to minimise missed appointments. They contacted women 24 hours in advance to remind them of the appointment and offered time to ask any questions they had about the process.

Staff ensured that women who did not attend appointments were contacted. At the point of booking women provided their preferred contact details and staff used these to reach them in the event they did not attend. Staff said they would refer to the local safeguarding team if they had concerns about a woman's welfare.

The service offered complimentary rescans in instances the sonographer could not obtain a clear heartbeat. There was a well-defined separation of this process from instances in which no foetal heartbeat was present, and the individual needed an urgent referral to an NHS specialist service. Where the sonographer found a heartbeat but could not secure a recording or image at the quality requested by the individual due to issues such as an empty bladder, the baby's position, or the woman's anxiety, they provided advice and offered a rescan at a later time and date.

Staff understood the impact of parenthood on women's partners and other members of their family. They provided support and signposting for dads-to-be and gave them time in appointments to discuss their needs. The service had an agreement with a paternity testing organisation and supported men to access this.

Meeting people's individual needs

The service was inclusive and took account of women's individual needs and preferences. Staff made reasonable adjustments to help women access services. They directed women to other services where necessary.

The ethos of the service was to meet individual needs. The registered manager understood the importance and personal significance of gender baby scans and tailored the service to each individual woman and their loved ones.

Some women wanted a scan to reveal the gender but to keep this information secret for a family event or gender reveal party. In such cases, the sonographer ensured screens were facing away from the woman during the scan so they could not see the gender. The office manager then provided a gender-neutral gift that would reveal the gender only when opened.

Staff ensured they fully understood each woman's needs and preferences before a scan. This information was collected through the online booking form and staff reconfirmed it when the baby arrived. Where women were undecided as to whether they wanted to know the gender, the sonographer worked with them to provide support during the process and ensure they made the right decision for them.

After scanning, the service provided printed and digital scan images to women. Digital images were available through a secure app, which women had access to shortly after the scan. This enabled them share images as they saw fit.

The service arranged interpreters for women with advance notice and women could note this on the booking form.

The service provided a patient guide in printed format in the clinic. Staff provided this electronically by e-mail on request and had it translated into other languages on an as-needed basis.

Staff had designed and refurbished the clinic with a focus on the needs and comfort of women. Filtered water, tea, coffee, and snacks were provided and staff maintained a selection of information on pregnancy services alongside products to enhance or promote wellbeing. The clinic had different seating areas, all furnished to a high standard with comfortable seating, and had frosted glass to the street to provide assurance of discretion and privacy. The scanning room was equipped with a large high-definition screen facing the scanning bed so that women could watch the scan in real time if they wished.

The clinic had a children's play area and a baby changing space.

The registered manager delivered services on demand to meet special requests and individual needs. For example, they had facilitated an out of hours scan so that a person's grandparent could attend around critical medical treatment.

Access and flow

People could access the service when they needed it. They received the right care and their results promptly.

Patients booked appointments using the service's website. This provided information on types of scan available and clearly set out limits on scanning, such as minimum age and gestation requirements. Women completed a series of screening questions before they could select an appointment and had the option to contact staff if they had questions. Staff also offered appointments booked by telephone and required women to complete a pre-scanning health questionnaire on their arrival.

The service had not cancelled any scans in the previous 12 months due to operational reasons. The only cancellations occurred when women presented outside of the safe scanning term of their pregnancy. The pre-screening process was designed to avoid this, but the service found sometime women provided inaccurate information that meant they could not scan.

The service pre-booked courier collection for blood samples for NIPTS and early gender DNA tests. This ensured samples reached the laboratory within the timeframe needed for an effective scan.

Good

Diagnostic and screening services

Staff offered a flexible scanning service to fit around women's other commitments, including weekend and evening scans.

Women paid a deposit at the time of booking to secure an appointment and as part of a strategy to reduce instances of wasted appointments by those who did not attend. This helped ensure the service offered choice and flexibility of appointments. Monitoring by the service indicated it was effective, with a 1% DNA rate in the previous 12 months.

Learning from complaints and concerns

It was easy for people to give feedback and raise concerns about care received. The service treated concerns and complaints seriously.

Women and those accompanying them knew how to complain or raise concerns. Information about the complaints process was on display in the clinic and accessible on the service's website. The service was a member of the Independent Sector Complaints Adjudication Service (ISCAS) and would direct patients to them for mediation in the event the registered manager could not resolve a complaint.

Staff understood the policy on complaints and knew how to handle them. There had been no complaints in the previous 12 months and all feedback was positive.

Is the service well-led?

Good

We have not previously inspected the service. We rated well-led as good.

Leadership

The registered manager had the skills and abilities to run the service.

The registered manager was the business owner and the sonographer. Along with the office manager, they understood and managed the priorities and issues the service faced. They were visible and approachable in the service for women and their families.

Both managers had extensive qualifications and training in NHS and private healthcare, with years of experience working in a private baby scan clinic, acute hospitals, a residential care home and a GP surgery.

Areas of responsibility and accountability were clearly defined between the registered manager and office manager. The team worked collaboratively together, in an environment that promoted respect and high standards of care.

Vision and Strategy

The service had a vision for what it wanted to achieve and a strategy to turn it into action. The vision and strategy were focused on the sustainability of the service and driving improvements in baby scan standards across the region.

Good

Diagnostic and screening services

The registered manager had developed objectives for the business and quality aims for the standard of care. They used peer reviews, membership conference attendances, and feedback from women to benchmark progress holistically and ensure standards were maintained.

The service vision focused on providing an "outstanding ultrasound experience for all pregnant women and their families with a unique service…" The team offered a wide range of services through partnerships with specialist organisations, which helped offer women options beyond scanning. The strategy was based on utilising the latest understanding of live bonding and scanning technology to provide women with assurance that care was the most up to date available.

Culture

Staff respected, supported, and valued each other. They were focused on the needs of women receiving care.

We observed a mutually respectful and supportive culture between the two members of staff. Both individuals were demonstrably passionate about their work and the standard of care provided and worked tirelessly to meet individual needs.

Staff spoke openly with women about the scans with the best results for their stage of pregnancy and planned outcomes. They provided advice when women requested scans that would not result in optimum images as part of an ethos of transparency.

Dignity, trust, and communication formed core elements of the service's values and staff took every opportunity to put these into practice.

Governance

The registered manager operated effective governance processes. Staff were clear about their roles and accountabilities and worked closely together.

The registered manager had developed clear governance protocols that reflected the nature of the service. For example, while they carried out blood tests for non-invasive prenatal screening (NIPTS), an independent laboratory was responsible for screening, providing results, and following up with each woman. The service had a standard operating procedure for this and made sure women fully understood it before agreeing to carry out NIPTS. Similarly, the service made it clear scanning was not diagnostic by nature and that women's maternity care remained with the NHS or their main private provider.

The service had appropriate policies and procedures to support the delivery of care. These were signed and dated, and the registered manager used a rolling review programme to ensure they remained up to date.

The clinical quality and governance framework detailed the standards of care patients could expect, the ethos of the service, and the responsibilities and accountabilities of staff. Staff used a quarterly governance meeting to review processes and minutes indicated they acted on feedback and audit results to implement change.

Management of risk, issues and performance

The registered manager used systems to manage performance effectively. They identified and acted on relevant risks and issues. They had plans to cope with unexpected events.

The registered manager maintained a risk register that reflected the nature of the service. At the time of our inspection there were 7 risks, each of which had an accountable person with details of mitigation and controls. Risk management reflected learning from incidents.

The service made it clear to women, through pre-scan discussions and consent documentation, that scans were for reassurance and bonding purposes and did not replace diagnostic scans provided on NHS maternity pathways. Women signed an understanding that they needed to attend planned NHS appointments and the scans provided at this provided were not a replacement for them.

The provider had a business continuity plan, which either member of staff could implement in the event of unexpected interruption to the service. The plan included a reciprocal arrangement with another British Medical Ultrasound Society (BMUS) registered clinic and provided women with the option of undergoing their planned scan at the alternative clinic or rebooking with this service.

Information Management

Information systems were integrated and secure.

The service had an up-to-date information and data management plan that incorporated their responsibilities under the Data Protection Act 2018 and the General Data Protection Regulations (GDPR). The service managed electronic data using secure cloud-based systems. This included the use of an app for women to access their scan images. Scan images remained the property and responsibility of the service and electronic transmission took place only to enable women's access.

The registered manager archived images as part of a policy to ensure they had access to information in the event of a future complaint or investigation. The archiving process was compliant with the General Data Protection Regulation (GDPR).

Staff worked within a retention and disposal of information policy that included guidance to adhere to Information Commissioner's Office (ICO) requirements. The provider was registered with the ICO to provide assurance to customers of safe data management.

Engagement

Staff actively and openly engaged with women and local organisations to plan and manage services. They collaborated with partner organisations to help improve services for women.

The online booking system ensured women had access to comprehensive information in advance of a scan. This included minimum pregnancy terms for each type of scan and detailed information on the differences between scans, expected results, and costing. The system automatically contacted women after each scan to ask them for feedback. The service maintained a consistently good survey completion rate of 30% and the maximum five-star rating, including for those who would recommend the service.

The registered manager and office manager had built good working relationships with NHS trusts in the region. This helped to improve understanding of the differences in their respective services and break down preconceptions about private baby scan services. This engagement resulted in good relationships with NHS services such as early pregnancy

assessment units (EPAUs) and neonatal services, which promoted access for women on referral by the sonographer. Staff noted each NHS trust had different criteria for accepting referrals as well as different requirements for the contents of referrals. The sonographer maintained open dialogue with key contacts at each trust to ensure the referral process was smooth when women needed it.

The service had an impact and reputation beyond the local area and women often travelled considerable distances for scans. A woman who recently underwent a scan noted, “I travelled a long way to get here, I wouldn’t go anywhere else.”

Comments from women who had used the service were persistently good. Recent feedback included, “Thank you for always going above and beyond,” and “Cannot recommend enough.”

Staff engaged with women to improve their knowledge of safe scanning and pregnancy practices. For example, a woman had approached the service following a scan at 8 weeks gestation carried out elsewhere. As this was below the safe recommended stage of pregnancy to carry out a bonding scan, the sonographer worked with them to understand the reasons for this and how they could manage the process more safely.

Learning, continuous improvement and innovation

All staff were committed to continually learning and improving services.

The registered manager was committed to exploring the use of new technology to improve women’s experiences and offer new services. They had invested in new ultrasound equipment to offer state of the art 4D scans with cloud-based access to images, so women could share them with loved ones.

The team monitored international research in pregnancy care and baby scanning and worked with specialist organisations that developed standards and expertise in the sector. For example, the service provided information to women on a National Institute of Health Research project to help improve understanding and interventions for women who experienced suicide ideation during pregnancy. They also worked with an organisation that collected stem cells from newborn babies as part of a new international drive to reduce future mortality from disease and illness. This was an emerging area of care and staff monitored findings as they were published.